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EPAR summary for the public

Eptifibatide Accord

eptifibatide

This is a summary of the European public assessment report (EPAR) for Eptifibatide Accord. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Eptifibatide Accord.

For practical information about using Eptifibatide Accord, patients should read the package leaflet or contact their doctor or pharmacist.

What is Eptifibatide Accord and what is it used for?

Eptifibatide Accord is a medicine used to prevent a heart attack in adults. It is used in the following groups:

- patients who have unstable angina (chest pain caused by poor blood flow to the heart, that may occur at rest or without an obvious trigger);
- patients who have already had a non-Q-wave myocardial infarction (a type of heart attack), with chest pain in the last 24 hours and with abnormalities on the electrocardiogram (ECG) or signs of heart problems in the blood.

Eptifibatide Accord is given with aspirin and unfractionated heparin (other medicines that prevent blood clots).

The patients most likely to benefit from a treatment with Eptifibatide Accord are those at high risk of heart attack in the three to four days after the start of acute (sudden) angina. This includes patients who are having percutaneous transluminal coronary angiography (PTCA, a type of surgery to clear the arteries supplying the heart).

The medicine contains the active substance eptifibatide.

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Eptifibatide Accord is a 'generic medicine'. This means that Eptifibatide Accord is similar to a 'reference medicine' already authorised in the European Union (EU) called Integrilin. For more information on generic medicines, see the question-and-answer document here.

How is Eptifibatide Accord used?

Eptifibatide Accord should be given by a doctor who has experience in the management of heart attacks and angina and can only be obtained with a prescription. It is available as solutions for infusion (drip) and injection into a vein.

The recommended dose is 180 micrograms per kilogram body weight given as an injection into a vein as soon as possible after diagnosis. This is followed by a continuous infusion of 2.0 microgram/kg per minute which is continued for up to 72 hours, until the start of heart surgery, or until discharge from the hospital, whichever occurs first. If the patient undergoes a percutaneous coronary intervention (PCI or angioplasty, a surgical procedure that is used to unblock narrowed coronary arteries), infusion of Eptifibatide Accord can be continued for up to 24 hours after the procedure, with a maximum treatment duration of 96 hours.

Patients who have moderately reduced kidney function should receive a lower dose during the infusion. Eptifibatide Accord must not be used in patients with severe kidney problems.

How does Eptifibatide Accord work?

Eptifibatide Accord is an inhibitor of platelet aggregation. This means that it helps to prevent cells in the blood called platelets sticking together (aggregating). This sticking together of platelets is an important step in forming a blood clot, and when it happens in the blood vessels supplying the heart it can lead to a heart attack. The active substance in Eptifibatide Accord, eptifibatide, stops the platelets aggregating by blocking a protein called glycoprotein IIb/III on their surface that helps make them sticky. This reduces the risk of a blood clot forming and helps prevent heart attacks.

How has Eptifibatide Accord been studied?

The company provided data from the published literature on eptifibatide. No additional studies were needed as Eptifibatide Accord is a generic medicine that is given by injection and infusion into a vein and contains the same active substance as the reference medicine, Integrilin.

What are the benefits and risks of Eptifibatide Accord?

Because Eptifibatide Accord is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Eptifibatide Accord approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Eptifibatide Accord has been shown to be comparable to Integrilin. Therefore, the CHMP's view was that, as for Integrilin, the benefit outweighs the identified risk. The Committee recommended that Eptifibatide Accord be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Eptifibatide Accord?

A risk management plan has been developed to ensure that Eptifibatide Accord is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Eptifibatide Accord, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Eptifibatide Accord

The European Commission granted a marketing authorisation valid throughout the European Union for Eptifibatide Accord on 11 January 2016.

The full EPAR and risk management plan summary for Eptifibatide Accord can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Eptifibatide Accord, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 01-2016.